Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Tepezza™ (teprotumumab-trbw)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Approval of Tepezza was based on the OPTIC trial. In this trial, adults with Graves' disease and active moderate to severe thyroid eye disease were randomized to receive Tepezza or placebo every 3 weeks for 8 doses. There was a significantly higher proptosis responder rate at Week 24 in patients treated with Tepezza compared to placebo. Addition clinical trial data in patients with low disease activity, or CAS, achieved a statistically significant reduction in proptosis from baseline to Week 24 after receiving Tepezza compared to placebo. Evidence from an open-label extension trial provides evidence to support retreatment with Tepezza in select patients.

Food and Drug Administration (FDA) Approved Indications:

Tepezza (teprotumumab-trbw) is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease (TED).

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Tepezza for Members when the following criteria are met:

1. Documented diagnosis of Graves' disease

AND

2. Documentation of thyroid eye disease

AND

3. Prescribed by or in consultation with an ophthalmologist or endocrinologist

AND

4. Member is at least 18 years of age or older

Limitations

- None.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3241	Injection, teprotumumab-trbw, 10 mg

References:

1. Bartalena L et al. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy guidelines for the management of graves' orbitopathy. Eur Thyroid. 2016; 5(1): 9-26.
2. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT04583735, A study evaluating TEPEZZA treatment in patients with chronic (inactive) thyroid eye disease; 2024 Apr 26 [cited 2024 May 10]. Available from: https://clinicaltrials.gov/study/NCT04583735.
3. Davies TF. Clinical features and diagnosis of Graves‘ orbitopathy (ophthalmopathy). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on April 28, 2020).
4. Davies TF. Treatment of Graves‘ orbitopathy (ophthalmopathy). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on April 28, 2020).
5. Douglas RS et al. Teprotumumab for the treatment of active thyroid eye disease. N Engl J Med. 2020;382(4):341.
6. Douglas RS et al. Teprotumumab efficacy, safety, and durability in longer-duration thyroid eye disease and re-treatment OPTIC-X study. Ophthalmology. April 2022;129(4):438-449.
7. Ross DS et al. 2016 American Thyroid Association Guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. Thyroid. 2016; 26(10): 1343-1421.
8. Salvi M et al. Medical treatment of Graves‘ orbitopathy. Horm Metab Res. 2015 Sep;47(10):779-88.
9. Smith TJ et al. Teprotumumab for thyroid -associated ophthalmopathy. N Engl J Med. 2017;376(18):1748.
10. Tepezza (teprotumumab-trbw) [package insert]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; July 2023.
11. Weiler DL. Thyroid eye disease: a review. Clin Exp Optom. 2017; 100(1): 20-25.
12. Xu N et al. Comparative efficacy of medical treatments for thyroid eye disease: a network meta-analysis. J Ophthalmol. 2018; 2018:7184163.
13. Zhou X, Zhou D, Wang J, et al. Treatment strategies for Graves‘ ophthalmopathy: a network meta-analysis. Br J Ophthalmol. 2020;104(4):551.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC).

June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T), effective September 1, 2023.

Subsequent endorsement date(s) and changes made:

- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- May 14, 2024: Removed the following Limitation “Continuation of Tepezza beyond eight infusions is considered experimental/investigational and not medically necessary.” Removed the requirement for thyroid disease to be active (eff 7/1/2024).
- June 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.